Public consultation of the EFSA draft Guidance on nanotechnology

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efsa
European Food Safety Authority

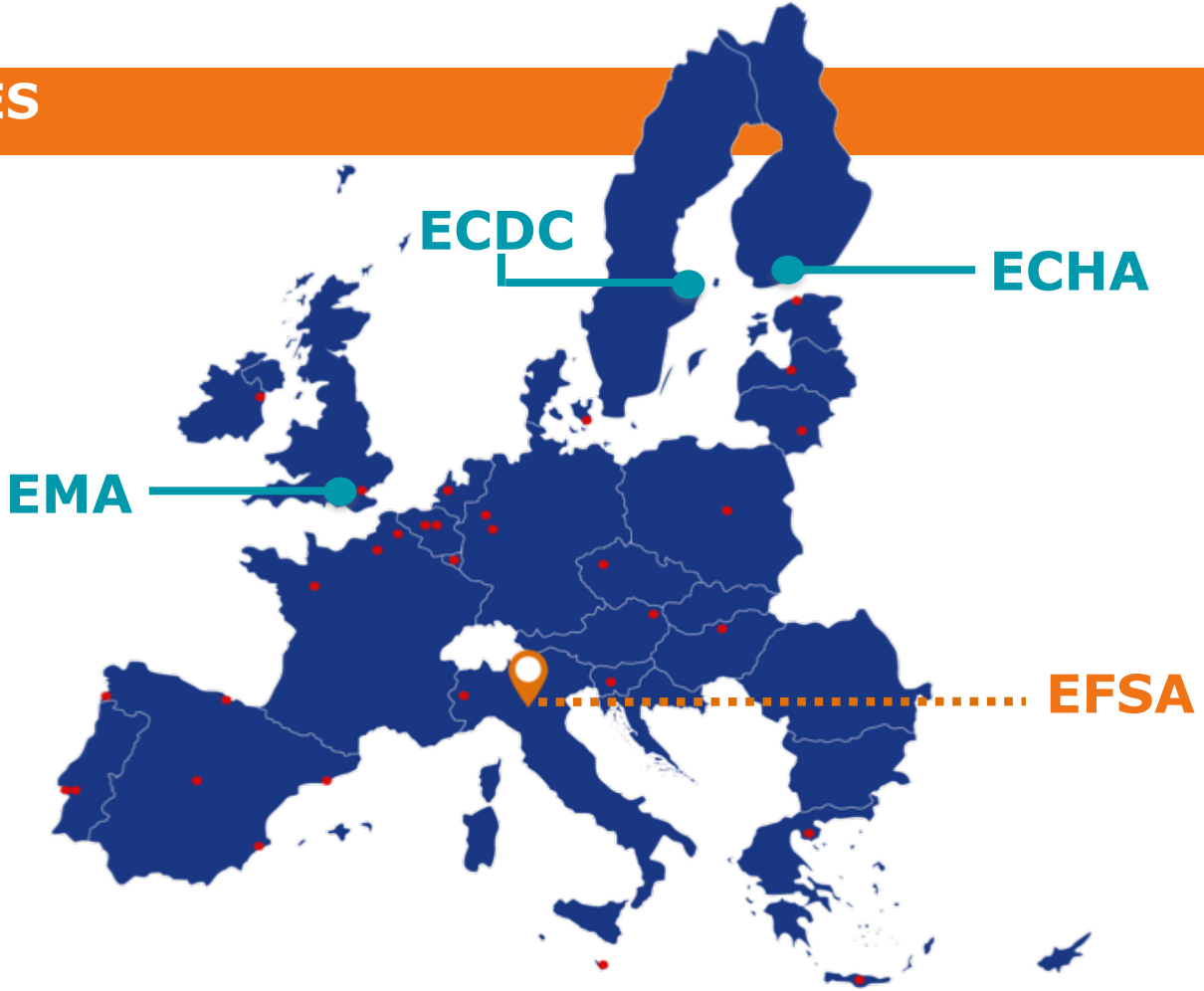
Outline

1. Short introduction to EFSA and experts

2. Timeline EFSA draft Guidance on Nanotechnology

3. Content of the draft Guidance

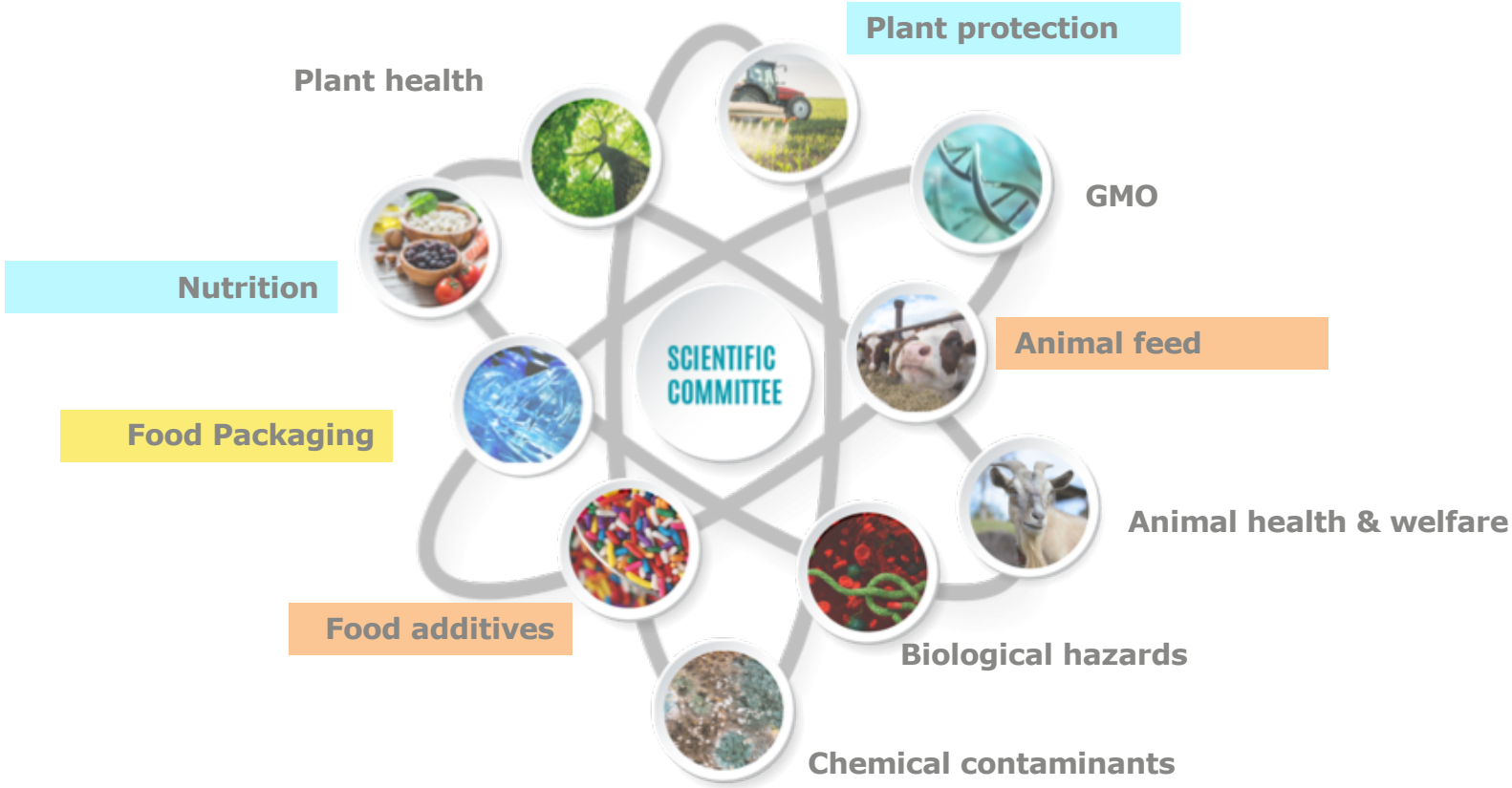
EU AGENCIES



EFSA staff

Coordinating the Working Group on Nanotechnology

THE SCIENTIFIC PANELS



THE SCIENTIFIC COMMITTEE WORKING GROUP

WG Member Experts :

- Alicja Mortensen
- David Gott
- Francesco Cubadda
- Agnes Oomen
- Qasim Chaudhry
- Stefan Weigel

EFSA Staff :

- Dimitra Kardassi (Pesticides)
- Maria Vittoria Vettori (Feed)
- Eric Barthélemey (FCM)
- Federica Lodi and Ana Rincon (food additives)
- Reinhard Acherl (Novel food)
- Reinhilde Schoonjans (Scientific Committee)

Ad Hoc Experts:

- Roland Franz
- Barbara Drasler

Observers:

- Hubert Rauscher

Timeline

- 2011 Original Guidance published
- 2016 Start update

- 2018 Public Consultation open from 12/01– 4/03
  - 34 interested parties
  - 367+ comments from Eu-survey and letters
  - 2 working group meetings to amend where necessary
- 2018 endorsement scheduled for May

Proposed Pilot Phase for 2018-2019

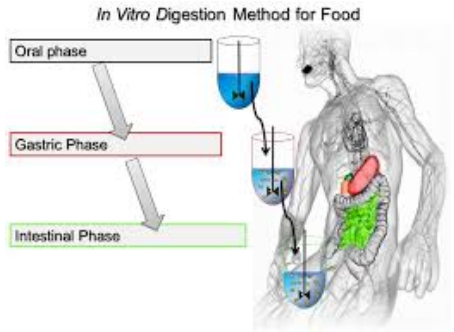
- September: testing phase with Panels and Units:
  - Novel food
  - Food additive / nutrient source
  - Food contact material
  - Pesticide
  - Feed additive
- November: Nano Network meeting with Member States
- January 2019: hearing with stakeholders
- June 2019: end Pilot Phase
- Autumn 2019: finalisation

GUIDANCE DEVELOPMENT

Two tasks for the working group

2016-2018: Update of 2011 guidance for **human/animal health** risk assessment.

2018 -2020: *de novo* development for **environmental** risk assessment.



Two principles

To supplement **existing sector-specific guidances**: there are entry points and exit points for applying the nanoguidance.

No tick box for core studies: there is a **tiered approach** in which not all studies are always required.

Clarifications and Amendments

- Clarifications on main themes:

The producer needs to test and it is claimed difficult to know in what food it will be used
Minimising Animal testing
Scope of our guidance/50% threshold materials
Nanodefine tools
Lysosomal degradation
Corona issues
12% in vitro degradation
Nanoform/variant
Biopersistence
Local effects
Uptake in genotox testing

- Shorten non-nanospecific information in reprotox, immunotox and neurotox sections
- Technical report of the public consultation will be published

Chapter 1 SCOPE and applicability of the Guidance

- Engineered nanomaterial (a.o. 1-100 nm) per definition of the Novel Food Regulation and the FIC Regulation
- Materials >100 nm which could retain properties of the nanosale
- Small fractions (<50%) in the size range <100 nm
- Different variants of nanomaterial
- Nanomaterial per EC Recommendation on a definition

Chapter 3

- Characteristics of the nanosale which may affect toxicity, e.g.
  - Altered hydrophobicity/hydrophilicity
  - Targeted or controlled release by the nanomaterial
  - Differerent or increased mobility in vivo (i.e. increased bioavailability and mobiliasation protential)
  - Interactions with biomolecules such as enzymes, DNA, receptor, potential Trojan horse effects
  - …..

CHAPTER 4 PHYSICOCHEMICAL CHARACTERISATION

Is relevant for

Decision as to whether the material has to be considered for nanospecific risk assessment under this Guidance

Full determination of the physical and chemical identity of the pristine material

Physicochemical characterisation of the material in test media used in toxicokinetic and toxicological studies, which is needed before, during and after the studies

Physicochemical characterisation of the material in complex matrices e.g. product formulations, which is needed for exposure assessment

CHAPTER 4 PHYSICOCHEMICAL CHARACTERISATION

Parameters

Table for the overall material
(e.g. composition and purity, agglomeration/
aggregation state, shape)

Table on the chemical componenets (e.g. chemical name, crystal form)

Extrinsic properties of the material as used on the market (e.g. solubility, dispersibility, reactivity)

Methods: Appendix C

Quality ensurance: validation and reference materials

Chapter 5 Exposure

- Mainly oral exposure; dermal and inhalation also for feed additives and pesticides
- Direct or indirect exposure
- Step-wise procedure with with exit points (back to the relevant EFSA guidances for conventional materials)
- If nanomaterial is present: quantification, characterisation and exposure estimation is needed

Chapter 6 Hazard identification and characterisation

- Stepwise framework
  - Step 0: in vitro degradation tests
    - Gastrointestinal digestion
    - Stability in lysosomal fluid
  - Step 1: existing information and in vitro
  - Step 2: (pilot) in vivo studies
  - Step 3: targeted in-depth investigations

Chapter 6 Hazard identification and characterisation

- Attention while testing nanomaterial
  - Agglomeration/aggregation
  - Metrics
  - High concentrations/doses
  - Demonstration of exposure
  - Mode of action
  - Controls
  - Corona formation
  - Feed/drinking water or gavage
  - Fresh dispersions for testing
  - …

Chapter 7 nanospecific risk characterisation

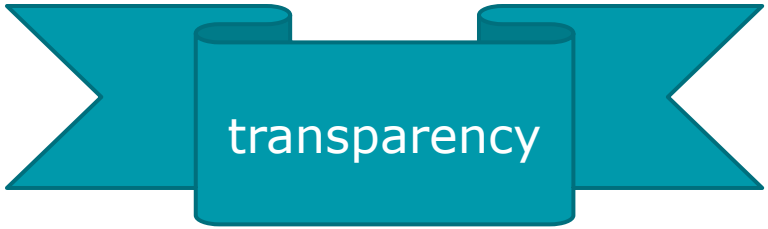
- Qualitative and if possible quantitative
- Explain assumptions and uncertainties
- Weight of evidence

- There should be a complete correlation between the material as produced and as tested
  - Batch to batch variation, aging, size distribution covered in the risk assessment

Chapter 8 Uncertainty descriptions

The guidance descibes how to reduce uncertainty:

- Due to scope (cfr. legal framework)
- In physicochemical characterisation
- In exposure assessment
- In hazard characterisaton
- In risk characterisaton



Concluding remarks

- Based on this Guidance, state of the art and alerts for testing nanomaterials can be found, as well as the requirements to meet the Food Laws
- It is the responsibility of the principle investigator to design the relevant test battery and describe the rational for it
- In order to minimize animal testing, a tiered approach including in vitro tests has been provided. Directions are given, but further research is needed, also for read across and in silico modelling approaches

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